(b) whether Government is aware that some colleges have been demanding capitation fee under different names;

(c) if so, whether an inquiry has been conducted against such colleges and the colleges de-recognised; and

(d) if not, the reasons therefor?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (d) On the basis of newspaper reports that two medical colleges in Tamil Nadu namely, Sri Ramachandra Medical College, Porur (Deemed University) and Sri Balaji Medical College, Chennai (Deemed University) were allegedly demanding capitation fees, the Central Government sought reports from the Government of Tamil Nadu and the Medical Council of India (MCI). The Government of Tamil Nadu have replied that notices have been issued to these two medical colleges but reply is awaited. Government of Tamil Nadu have further stated that action would be taken against aforesaid two medical colleges on the receipt of their replies. The MCI constituted an Inquiry Committee to investigate into the matter. The Committee has since submitted its report to the Central Government which is under consideration.

Strict norms for controlling private medical colleges

215. DR. (SHRIMATI) NAJMA A. HEPTULLA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) what recommendations have been made by the Knowledge Commission concerning health care education system in the country;

(b) how many recommendations have been accepted by Government so far;

(c) what are the reasons for not accepting recommendations of the Knowledge Commission;

(d) whether Government will review existing medical education system and enforce strict norms for private medical colleges; and

(e) if not, the reasons therefor?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) to (e) The main recommendations of the Knowledge Commission are as follows:

- Constitution of a Standing Committee within the structure of the Independent Regulatory Authority for Higher Education (IRAHE).
- The Indian Medical Council Act should be amended such that MCI functions only as a professional association, with powers to conduct nationwide examinations, and to provide licenses for those who wish to join the profession.
- Similar changes are needed for all the other Councils *viz*. Nursing Council, Pharmacy Council, Dental Council and Rehabilitation Council.
- IRAHE should be empowered to license suitable agencies for accreditation.

- Policies of admission and fee structure of private college have to be regulated, not only to stop them from becoming sources of political and financial power but also to arrest falling standards.
- All institutions must constitute Curriculum Committees that plan curricula and instructional methods, which are regularly updated.
- Attracting and retaining quality faculty should be accorded top priority. Measures such as opportunities to attend international conferences regularly, sabbaticals, dual appointments, regarding research, fast-track promotions, and dissociating remuneration from Government pay scales should be explored.
- The medical profession needs to be structured like a pyramid with the base made up of general physicians. At present there is little if any space for such doctors in postgraduate courses, Therefore.
- Adequate representation should be given to general physicians while carrying out expansion of post graduate seats such that fifty percent seats are reserved for general physicians.
- New streams for post graduation should be looked at based on needs.
- Admission to post graduate courses should be done on the basis of credits received in the National Exit Examination and pre and post internship clinically oriented exams after internship.
- Need to reserve post graduate seats (upto 20% of total available seats) for graduates who have worked in rural areas for at least 3 years.
- The number of medical colleges in relation to population in some states is much higher than in other states. The Central Government should aid new colleges in these states to address this regional disparity. For instance, north eastern states require urgent attention in this context. The Central Government can develop a list of priority sites for establishing new colleges where the impact of new clinical facilities would benefit the surrounding rural population.
- Further at least one institution should be identified in each State that can serve as a center of excellence and role model for the other institutions of the state.
- Medical education cannot be standalone. It requires support in the form of trained nurses, pharmacists, paramedic workers. It must all also serve the essential purpose of delivering health care to the people. Therefore, we also set out some recommendations on education for supporting services and public health.

The recommendations of Knowledge Commission are under consideration. However, this Ministry proposes to set up a National Council for Human Resources in Health as an overarching regulatory body for the health sector to reform the current regulatory framework and enhance

supply of skilled personnel. A Task Force under the chairmanship of Union Secretary (Health and Family Welfare) has been constituted to deliberate upon the issue of setting up the proposed National Council. The Task Force shall submit its report to the Ministry by 31st July, 2009.

Human clinical trials

216. PROF. ALKA BALRAM KSHATRIYA: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether Government has mandated all human clinical trials being done in the country to be registered with the Indian Council of Medical Research (ICMR);

(b) if so, whether the offenders of unethical trials and those who violate the norms would be punished;

(c) if so, the details thereof; and

(d) the details of unethical human clinical trials came to the notice of Government during the past few months and action taken by Government thereon?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) Prior to 17th November 2008, registration of clinical trial was voluntary. For all the clinical trials, permission of which were granted between 17th November 2008 to 14th June 2009, applicants were advised to get the trials registered at Indian Council of Medical Research (ICMR) registry at *www.ctri.in.*. However for all clinical trials permitted on or after 15th June 2009, applicants are being informed that it is now mandatory to register the trial at the said ICMR site before enrolling first patient in the study.

(b) and (c) Under Rule 122DB of Drugs and Cosmetics Rules, if any applicant fails to comply with any of the conditions of clinical trial permission, Drugs Controller General (India) can suspend or cancel the permission.

(d) The inspection of one of the sites of a clinical trial by a team constituted by Central Drugs Standard Control Organisation (CDSCO), revealed various Good Clinical Practices (GCP) violations. Therefore, the concerned investigator, sponsor and monitor were issued warning letters asking them to take corrective actions to prevent such violations in future. The clinical trial remained suspended at all the twelve sites from 06.11.2008 to 22.04.2009. The sponsor submitted various corrective actions taken to ensure GCP compliance. CDSCO scrutinized the same and decided to revoke the suspension on 23.04.2009 from all the sites except the inspected site. Further monitor and investigator of the inspected site also submitted details of corrective actions taken by them, based on which the suspension from the inspected site was also revoked on 02.06.2009.